BREAKING DOWN BARRIERS IN HEALTHCARE

AN URGENCY FOR THE CLINICAL LABORATORY TO MOVE TO THE FOREFRONT OF PATIENT CARE
Healthcare systems are consolidating, budgets are under more pressure than ever, new payer models are beginning to surface, and patient volumes are increasing worldwide. While the challenge of navigating these uncharted waters is formidable, a wealth of data, information, and analytics exists to help healthcare systems not only manage adeptly in the current environment, but also to thrive and flourish in the future. That data is available today, and it is available from your clinical laboratory.

However, fully leveraging that data will take a shift in how most of us think about and view the lab. Instead of looking simply at throughput, turnaround time, or the variable cost per test, healthcare systems with an eye to the future will need to take a holistic view of the total value a laboratory can bring and how it can add more value throughout the care process. When leveraged correctly, the clinical laboratory can greatly assist healthcare systems to achieve better operational efficiency, as well as integrated clinical care excellence.

Abbott Diagnostics commissioned the Economist Intelligence Unit and Ipsos Healthcare to dig deeply into the perceptions and capabilities of the clinical laboratory, as well as the role it plays. The research was conducted among healthcare executives, physicians, patients, and pathologists. As you will see in this paper, the data illustrates the path forward is to change the often commoditized positioning of the lab to one that allows for the multitude of benefits the lab can offer. The research also indicates that stakeholders are ready and willing to integrate the lab into the shift toward value-based healthcare, with healthcare executives believing the future of the lab’s role in better decision making is not only necessary but inevitable.

We found the data to be eye-opening, and we are publishing this paper to challenge the status quo, stimulate dialogue, and ultimately act as a catalyst to improve processes and patient care.
PREFACE

As you read through this compelling body of work and review the strategic insights brought forth, please keep in mind the following questions to further stimulate dialogue within your healthcare system:

- Do you have a three-year lab strategy that ties into corporate metrics, such as patient satisfaction and lower readmission rates?
- Is your lab proactively consulting with physicians on test results and complex cases to help deliver clinical insights for better outcomes?
- Does your healthcare system aggregate data from the lab to generate insights, and are those insights proactively shared across functions?
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary</td>
<td>5</td>
</tr>
<tr>
<td>Introduction</td>
<td>8</td>
</tr>
<tr>
<td>Chapter 1: Nature Of The Problem</td>
<td>10</td>
</tr>
<tr>
<td>Chapter 2: The State Of Clinical Laboratories Today</td>
<td>15</td>
</tr>
<tr>
<td>Chapter 3: Opportunities And Challenges</td>
<td>20</td>
</tr>
<tr>
<td>Chapter 4: The Way Forward</td>
<td>29</td>
</tr>
<tr>
<td>About This Report</td>
<td>32</td>
</tr>
<tr>
<td>References</td>
<td>33</td>
</tr>
</tbody>
</table>
Dialogue around value in healthcare has given way to both hope for a brighter future and great consternation about the way it is managed today. Driven by converging forces—growing population health needs, limited resources, and advances in science and data analytics—the focus on how to adapt established systems to drive better patient outcomes and improved cost efficiencies has become paramount but difficult.

Among the talk and multitude of value initiatives, the clinical laboratory has largely been cast aside. This is surprising, given the lab’s overlap with core value principles of data, timely and efficient diagnosis, and patient-centricity. It is also indicative of a broader problem: a fragmented value chain that underexploits sources in decision making at a time when the health world’s stated focus is on outcomes. Thus, the lab’s marginalized position is invariably a driver of an unsustainable approach to health.

Nevertheless, as every aspect of the status quo in healthcare has been scrutinized and a more welcoming environment for new ideas has emerged, there is clear recognition among all stakeholders that the laboratory can be part of the long-term solution. Executives, physicians, payers, and patients recognize the lab can be a pivotal building block of an improved system:

• As a principal data repository used to improve decision making in a shifting landscape.
• With an abundance of clinical expertise, aligning patient needs to evidence-based solutions.

To put the laboratory at the forefront of care, however, requires overcoming well-entrenched processes and culture, hurdles that have held back true transformation over the past decade. For these reasons, research was conducted (and findings were presented in this study) to identify an actionable, achievable path for the lab to play an elevated role. Extensive interviews with global stakeholders and expert insights serve as the basis for determining the current reality and future possibilities for the lab, all in the context of the value-based healthcare movement.

*Evidence-Based Laboratory Medicine. The Clinical Biochemist Reviews, 2013.

It is estimated that 70% of all healthcare decisions affecting diagnosis or treatment involve a pathology investigation .... [D]iagnosis, treatment, and subsequent therapeutic monitoring are often dependent on a range of pathology-based results.

A survey of senior hospital executives indicates the clinical laboratory is in the top three functions for achieving improved KPIs, the most influential in health informatics infrastructure, and an untapped source for greater value.
Key findings

The current reality of the laboratory is a lack of integration and empowerment

The research clearly indicates a subordinate role for laboratories in healthcare. Labs continue to be treated mostly as a commodity by key stakeholders, as evidenced by the perceived low value on the part of healthcare professionals (HCPs) and the dwindling investment levels of payers, providers, and governments. Even more troubling is the current disconnect between defined laboratory success—measured in great part by operational efficiency metrics—and impactful, outcome-related key performance indicators (KPIs).

The root cause of this reality is multifold and reflects differing perceptions of stakeholders, including conflicting beliefs. Lab directors and HCPs see the immense value of the knowledge generated by labs, but they cannot seem to overcome the historical one-sided communication flows. Executives and payers recognize the importance of the clinical laboratory in achieving organizational objectives; yet they lack awareness of current dynamics and their inability to execute their stated convictions.

Greater maturity around value in health opens a window to elevate the lab's role

Despite the alarming current environment, a clear window of opportunity exists for labs to take a more prominent position in achieving value-driven healthcare goals. Part of this prospect is based on a recognized need across stakeholders for better and more timely evidence to support decision making. The unstoppable trend toward data-driven analysis, combined with a constant stream of vital patient data, places the clinical laboratory at the center of the analytics movement.

Even more striking is the potential for the lab to act as a bridge between different stakeholders in the healthcare ecosystem. From more active and informed patients to HCPs overwhelmed by the weight of existing (and at times conflicting) evidence, or payers and governments seeking earlier, more preventive interventions, the lab's role in disease-agnostic pathology appears critical. While this requires both integration in KPI setting and care decisions, along with evidence that links lab activities to core outcome goals, the environment seems prime for this radical shift.

The need to adapt represents both opportunity and risk for the clinical laboratory

In the end, it is clear that with this core element in clinical decision making relegated to the margins, there is a severe limitation on the progress of value-based healthcare, unless we can shift the paradigm in which labs operate today. If all stakeholders are able to match their willingness for change with action, however, the result will be improved diagnosis and resource utilization, giving healthcare management an opportunity to catch up with advances in science and technology.
As an *Economist* cover story in February 2018 illustrates, a “revolution” is indeed coming to healthcare, with patients, technology firms, and data all set to take center stage while legacy participants also are calling for change. On the surface, this should be a boon for laboratories: With nearly 8 billion test results processed and nearly 70,000 genetics tests available in the United States alone, the primary source of everything from cholesterol levels to cancer markers should prove invaluable.

Yet, the recent past of seismic shifts in other industries should serve as an impetus to act. Retail, travel, and media have all seen their landscape turned upside down, with the pace of change accelerating every year. The telecom sector is an apt warning for healthcare: A span of two decades saw not just a dramatic swing in communication media (fixed to mobile to video to social), it also witnessed nimble technology-centric new entrants rendering previously strong incumbents across the value chain to secondary or, worse, insignificant positions.

Thus, the lesson for labs is simple: Disruption in healthcare will impose change, and those who do not evolve their business models by constantly adding value (especially as the complexity of care increases) will eventually experience a similar marginalization.

44% of C-suite executives surveyed believe that it is likely that they could outsource the clinical laboratory function if it generated less revenue or if it were negatively affected by a reimbursement cut.
The study: Fostering an enabling environment for the lab’s impact on the value-based healthcare (VBHC) movement

This study started with two basic questions: What is the reality of the clinical laboratory today, and what should its role be in the VBHC movement? “Breaking Down Barriers in Healthcare” is a report by Abbott aimed at answering these questions. Written by the Economist Intelligence Unit (EIU), supported by research partners Ipsos Healthcare and Acuity Marketing Research, this study examines the lab’s current influence on value-related goals and perceptions of key stakeholders (and the existing tensions between them) and also explores initiatives that could increase the lab’s impact on the overall patient-care pathway.

To generate the insights captured in this study, the research followed a three-pronged methodology:

• Framing key issues – The research identified the underlying drivers and gaps in the clinical laboratory’s role today. This analysis included such factors as the use of KPIs and linkage to patient outcomes, integration of laboratories with other stakeholders in care, and the state of skill sets in data analytics.
• Quantitative surveys and primary research – The research engaged the expertise of noted industry thought leaders and practitioners, lab directors, HCPs, senior executives, and patients globally to gain insights on current behaviors and established perceptions.

• Defining priority areas – Conclusions then were drawn from the research results and established knowledge in diagnostics, VBHC, and the overall healthcare environment. These findings served as the basis for identifying a path forward for an expanded role for laboratories in optimal decision making across the healthcare continuum.

The resulting output of unique data sets and expert insight is evidence underpinning the need for the clinical laboratory to be an equal stakeholder in the future value equation and showing the limits imposed by today’s fragmented environment, care inefficiencies, and sub-optimal outcomes.

Chapter 1 explores the underlying currents holding back the value movement while Chapter 2 explores interactions with labs today and established stakeholder views. This modus operandi has severe implications for patients and health systems, reflected in numerous value leakages.

Chapter 3 offers a vision for the role of the clinical laboratory in value-based healthcare, in which its alignment and integration can generate both better outcomes (from clinical and patient views) and systemwide efficiencies. While this assessment recognizes difficult barriers to overcome, the road map is, nevertheless, necessary and attainable.

Chapter 4 concludes with a call to action across stakeholders, recognizing that opportunities for improvement are within reach and that maintaining the status quo is simply not an option.
Value in healthcare is a growing trend, but it lacks measured progress

Over the past decade, “value” has been one of the most discussed (and at times overused) terms in healthcare. First described in 2006 by Michael E. Porter and Elizabeth Olmstead Teisberg, it has become synonymous with better decision making through outcome-focused evidence, cost efficiencies, and integrated patient-centric care.

The impetus for such a radical shift in healthcare is well known. The promise of medical science and data analytics has ignited the drive for more precise and informed decision making. The remarkable progress in health innovation has been witnessed across the sector’s ecosystem, from improved availability of accurate diagnostics to growth in precision drug therapies and the rise of new technologies, such as fitness wearables.

At the same time, variations in care and financial pressures have exposed substantial weaknesses. With global healthcare spending growing at an annual average rate of 7 percent (more than double economic growth), aging populations and an increasing incidence of chronic diseases lead to questions about the sustainability of today’s healthcare cost pace.

The result has been greater scrutiny of current health systems. Some of this focus has resulted in forward-looking policies. In the EIU’s recent review, each of the 25 countries studied was found to have already established, or to be in the process of adopting, at least some value-related building blocks in its systems. Moreover, this drive toward VBHC is not reserved to wealthier economies; countries such as China, Turkey, and Mexico have made as many strides (or even more) in national coordinated care programs as Western European nations have.
Yet, neither increased spending nor pockets of change toward value have translated into a return on investment, as shown in Figure 1. According to WHO disability adjusted life year (DALY) data, this gap actually worsened slightly in the United States (2 percent) from 2010 to 2015, with other large, advanced economies, like the German and Japanese economies, experiencing similar changes.

While this lack of outcome improvement can be attributed to a variety of factors, it highlights underlying misalignment between care delivery and population health needs. A principal culprit of this disconnect has been around decisions made to satisfy immediate demands. Though the term “value” is mentioned as the underlying goal for multiple stakeholders, this concept has morphed into dangerous territory, either through cost containment measures or in support of individual entrenched positions. Case in point: Despite the overwhelming evidence of stakeholder misalignment and non-impactful spending, the same EIU VBHC study identified only one country, Sweden, that has taken the dual steps of promoting bundled payments and developing mechanisms that identify interventions for de-adoption.6

In line with this, a core challenge is the constant evolution of the definition of value itself. Initiatives, such as value frameworks and outcome-based incentives, have attempted to codify and quantify the economic, health, and patient quality-of-life impacts of different health technologies and interventions, but these steps represent just a starting point, as the implications of health touch multiple aspects of society. The EIU work in this field (from the impact of healthy populations on overall economic growth7 to the positive impact on productivity from the adoption of new health technologies in Japan8) reflects the broader
consensus that value metrics cannot be limited to either short-term time dimensions or just health benefits. Without a dynamic view on value measures, risks will persist, with short-term demands outweighing long-term paybacks.

**Big data and informatics are major topics of discussion; benefits are yet to come**

A critical tool for transforming health systems into a value-based approach is fully harnessing the potential of data and analytics. The much-publicized effort regarding the use of data in healthcare—in industry, among providers, and across payers, public sector entities, and new entrants—has produced a tsunami of activity and set high expectations for future progress. Even patients are set to play a major role in this development, as data allows patients to monitor their health, manage complex conditions, spot errors, and help aggregate valuable metrics.⁹

Yet, despite the hype around big data and clear recognition of it as a building block for value, it still faces a number of basic hurdles before being able to fulfill its potential for systemwide impact:

- Lack of standards regarding costs, clinical outcomes, and results that matter to patients
- Growth in data silos, especially as different entities (disease-specific organizations, technology firms) begin to enter this space and generate their own primary data
- Security concerns and the ability to share valuable data but still maintain patient privacy

Advanced economies, given their technology infrastructure and greater maturity in data analytics, have led the way in attempting to overcome these issues, but the numerous cases of success, which tend to be limited in size and therapeutic reach, have not resolved overarching weaknesses. In the EU, myriad initiatives concerning big data across member states have not been put into a “coherent conceptual framework,” which, in turn, hinders health policy and research objectives.¹⁰ The problem becomes more profound in an emerging market environment, with a lack of proper systems and even basic databases, such as disease registries.

Without an organized approach toward integrating efforts under a common platform and understanding, individual stakeholders have been left to fend for themselves among a growing sea of structured and unstructured data. This will worsen over time, as the plethora of real-time information overwhelms doctors and potentially misleads patients. A recent survey, for instance, revealed that, while 22 percent of physicians at a major U.S. cancer center expressed “low confidence” in their knowledge of genomics, an astounding 42 percent were willing to share uncertain findings of genetic testing with their patients.¹¹

“Data needs to be organized and made consistent and credible in a way that’s rapidly analyzable.”*

*Dr. Amy Abernethy, Chief Medical Officer, Flatiron Health

The plethora of real-time information overwhelms doctors and potentially misleads patients.

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The lab’s impact on the value equation: minimal today, exponential tomorrow?

If the value movement can be characterized as developing yet incipient, the clinical laboratory’s role in this process has largely been left on the sidelines. Consider the following points as indicative of the lab's context today:

- Little discussion in literature – A search of established literature on VBHC indicates labs are mentioned in 1 percent of studies.12
- Tests treated as commodity – Despite the increase in volume, Medicare Part B expenditures on laboratory tests fell from $7 billion in 2014 and 2015 to $6.8 billion in 2016.13
- Differing stakeholder views – While executives believe the laboratory is a critical cog in delivering desired results, less than 50 percent of HCPs see it as a valuable resource.14

These and other facts show laboratories are neither treated nor viewed as primary components in the value dialogue. Figure 2 demonstrates this existing divide, leveraging the EIU’s established VBHC framework (consisting of four core pillars), opportunities for lab impact, and the existing gaps today. From this, it is clear there are sizable shortfalls regarding better decision making, efficient use of resources, and patient outcomes.

Figure 2: Repercussions from the lab’s secondary role in VBHC trend

<table>
<thead>
<tr>
<th>VBHC Pillars for Success</th>
<th>Opportunity for Lab to Impact VBHC Equation</th>
<th>Perceptions of Lab’s Role Today</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ENABLING ENVIRONMENT</td>
<td>VBHC Principle: Ongoing Education</td>
<td>18% of lab directors regularly provide training in diagnostic interpretation.</td>
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<td></td>
<td>60% of HCPs would like to receive regular training from clinical laboratories in diagnostic interpretation.</td>
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<td>2. MEASURING RESULTS</td>
<td>VBHC Principle: Results</td>
<td>28% of typical tests ordered are believed by doctors to be unnecessary.</td>
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<td>In the U.K., £2.5 billion is spent on pathology, with demand for 1 billion-plus tests growing annually by 10%.</td>
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<td>3. INTEGRATED CARE</td>
<td>VBHC Principle: Integrated Care</td>
<td>25% of tests involve doctors consulting with labs regarding test appropriateness.</td>
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<td></td>
<td>70% of all healthcare decisions affecting diagnosis or treatment involve a pathology investigation.</td>
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<tr>
<td>4. ALIGNED INCENTIVES</td>
<td>VBHC Principle: Outcome-Driven Goals</td>
<td>28% of labs feel they impact executives’ top KPIs (number of hospital-acquired infections).</td>
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<td></td>
<td>A majority of executives believe the lab is one of the important functions for delivering higher-quality care.</td>
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Source: 2017 Customer Engagement Survey by Ipsos Healthcare, EIU analysis.

“No other discipline in the healthcare continuum has a base of scientific knowledge similar to that of pathology.”

Director, NSW Health, Australia
While there are a variety of reasons for this (explored in Chapter 2), this marginalized role in today’s healthcare has serious implications. Even if only a fraction of the reported $200 billion in wasteful spending in the United States from unnecessary tests and medical treatment\(^{15}\) involves misuse of lab capabilities (across all participants in care), the impact in a resource-constrained world is significant.

This same conclusion, however, also indicates immense opportunity. With data at the center of better intervention choices and the lab serving as a key repository of such information, strong and timely evidence can help ensure impactful, outcome-driven decision making across the continuum. But this can go beyond simply eliminating waste: In a world where preventive care is becoming a policy priority, the lab can be a central figure in anticipating population health needs. This new paradigm of health management can, in turn, shift the value focus from “sick care” to “well-being.”
Commoditized role and positioning limit the laboratory’s impact on value

The research on the state of the clinical laboratory in the value movement presents a much bleaker picture than that of overall health systems.

First and foremost, there has been a largely singular focus on delivering value by achieving cost efficiency. This aim is reinforced by ongoing reductions in reimbursement levels in a multitude of markets. As seen in Figure 3 (on the next page), the decreasing pathology services spending share of the total Medicare Benefits Schedule (MBS) in Australia—from 16 percent to 12 percent—is striking when this represents three times the percentage of total services provided and healthcare spending per head rose annually at 9 percent during the same period.17

“What is frustrating is that laboratories have access to so much information, but despite this, decisions [across the care continuum] are made by gut.”

Daniel Leveson, National Health Service
This trend is not limited to just one country or region:

- In the United States, the new Protecting Access to Medicare Act draft rates for clinical lab test prices are just one example. The Centers for Medicare & Medicaid Services (CMS) stand to save nearly $700 million\(^{18}\) from lower payments for clinical laboratory diagnostic tests.

- In the U.K., spending per head on \textit{in vitro} diagnostics is half that of other comparable countries in Europe, despite demand for such services growing at 10 percent annually between 2014 and 2016.\(^{19}\)

- To make diagnostic tools available to a wide population in India, the country implemented a policy following the WHO’s Essential Diagnostic List (aimed at defining a group of \textit{recommended} \textit{in vitro} diagnostics for use in health systems\(^{20}\)), which includes providing free tests and setting reimbursement caps.\(^{21}\)

The divergence between increased volume and squeezed investment in labs is concerning. Not only has this lack of budget left little flexibility to adapt to the changing healthcare landscape, but the cost focus has dictated lab goals. Case in point: Only patient satisfaction was rated higher than clinical lab test turnaround time by laboratory directors, among 20 broader clinical, patient, and system KPIs.\(^{22}\)

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\(^{18}\) Source: Ernst & Young, Estimating the Pathology Productivity Dividend, 2016.
Confluence of stakeholder (mis)perceptions further marginalizes the lab’s role

Examine further the perceptions of and the established relationships with key stakeholders, a broader storyline becomes clear. As previously shown, the research indicates HCPs traditionally only initiate one-way interaction with labs, with very little consultation on choice of diagnostic testing and results interpretation. This transactional dynamic is due, in part, to a lack of belief by HCPs in a link between the lab activities and healthcare goals. Just 27 percent of HCPs surveyed feel the integration of lab personnel into clinical teams can have a significant impact on care. This preconception helps maintain the status quo, as the laboratory is not viewed as a critical component in achieving outcome-related healthcare objectives.

Unlike HCPs, the majority of executives surveyed believe labs do have the understanding, influence, and involvement to improve decision making, but these beliefs do not match up with reality.

Figure 4 highlights the contradiction between beliefs and practice; the lack of recognition of gaps in KPI alignment and data skills is apparent. A major culprit is simply the siloed nature of lab operations. For example, in the United States and the U.K., lab leaders note that labs are often separated from the rest of the hospital and are seen primarily as test-result providers. This has given rise to the outsourcing of laboratory functions, further feeding the disconnect among stakeholders.
This positioning also is reinforced by payer actions. Though stakeholders show a willingness to shift toward value (through efforts to link evidence with reimbursement for tests), short-term incentives and lack of definitive data hold back advancement. More importantly, perceptions regarding ongoing system inefficiencies and, at times, illogical expectations for resolving them before wholesale change can occur continue to dampen progress. In the words of one payer interviewed: “If reimbursement policies are to change, we must first see a reduction in the number of ‘unnecessary’ procedures conducted, a reduction in resource duplication, and a reduction in costs.”

All this context indicates a persistent misalignment in stakeholder perception of the clinical laboratory's overall influence and involvement along the patient-care pathway. Without sufficient integration in KPI settings, labs continue to focus on their own internal lab metrics and also lack the forum to present evidence on how their knowledge and output link to broader healthcare goals. Reconciling these differences, therefore, is key to creating a proper enabling environment for laboratories to elevate their role in the value-based healthcare world.

**Costly implications stem from the current marginalized role of laboratories**

The implication of a volume-driven system and stakeholder imbalance around the lab is poor decision making. With each stakeholder working on partial and imperfect information, undesired outcomes, including misuse of existing resources and less than optimal care, are inevitable.

Evidence concerning improper use of testing has qualified this impact. One research study determined that routine lab testing could lead to harmful externalities, with the case cited, nosocomial anemia onset, showing that nearly 20 percent of hospitalized patients developed “moderate to severe hospital-acquired anemia” from repeated blood draws that caused decreased hemoglobin levels.24

While test redundancy has garnered much attention, not leveraging the best diagnostic tool can equally affect outcomes. In fact, one study found the prevalence of underutilization was double that of overutilized testing.25 This potential for errors (or lack of detection) is significant, as demonstrated by a program conducting regular HbA1c testing for diabetes in emergency room settings in Australia that found nearly one in three people with diabetes was previously undiagnosed.26
The possible consequences of these gaps in care are reflected in the following medical literature:

- According to the Institute of Medicine, in the United States, diagnostic errors contribute to approximately 10 percent of patient deaths and upward of 17 percent of adverse events in hospitals.\textsuperscript{27}
- In New Zealand, delays in diagnosis have been associated with nearly 16 percent of serious primary care injuries and 50 percent of total annual patient deaths.\textsuperscript{28}
- In sub-Saharan Africa, almost 50 percent of patients with diabetes go undiagnosed—a trend, which, if not reversed, could be a key driver in generating an economic burden of US$59.3 billion by 2030.\textsuperscript{29}

These and other value leakages are not the fault of any one stakeholder, including labs. Indeed, one study found the testing process more prone to errors in the pre- and post-analytical phases,\textsuperscript{30} but without altering the dynamics surrounding labs, this core element in decision making restricts value. Missed chances for proper diagnosis and resource wastage will persist, and the opportunity to ensure the flow of insight and shared accountability will dissipate with increased complexity of care.
Environment ripe to elevate the clinical laboratory as part of the value solution

At its core, the term “value” attempts to encapsulate maximizing clinical and patient outcomes at the lowest possible cost. The EIU VBHC framework (as outlined in Figure 5) has translated this into clear steps for making better decisions, both for patients and health systems. Applied in multiple EIU analyses, from health systems assessment and cancer care in the United States to renal care in Latin America, this conceptual structure has proved helpful in framing complex value-related issues.

![Figure 5: Framework for health system alignment with VBHC](image)

How much more likely would the success of value in healthcare be with a more prominent role for labs in evidence-based decision making and patient outcomes?
To execute on these value principles, the entity directly involved in a high percentage of healthcare decisions needs to take a central role in system transformation, instead of the supportive transactional function laboratories play today.

No other entity in healthcare has the multidimensional patient and population data (on historical disease incidence rates and patterns), as well as the clinical expertise, to add value in diagnosis. This becomes even more invaluable as the complexity of care grows over time, including the range of new healthcare diagnostic tools.

The positive news is key stakeholders (executives, patients, HCPs, payers, and lab directors) are recognizing that the laboratory will be a vital node in a future sustainable and integrated healthcare value chain. Consider the following:

- More than half of executives surveyed expect an increasing role for the laboratory in such important tasks as test utilization management and predictive analytics.
- 40 percent of patients are seeking recommendations for additional testing or overall customization of their lab reports.
- 62 percent of HCPs believe clinical decisions rely on clinical laboratory medicine test results or recommendations.

In this sense, the environment appears to be conducive for the lab to take a major step in its role in achieving improved patient-centric value. This combination of future need and openness for change is demonstrated in Figures 6 through 9, which connect each of the EIU VBHC pillars to stakeholder expectations concerning future healthcare needs and areas of impact for the clinical laboratory.

Empowering the clinical laboratory through enabling tools and culture reset

The growing needs of the healthcare system and the current openness of all actors to rethinking how healthcare is delivered efficiently represent a starting point for the lab in achieving an elevated position. To do so successfully, all participants must address the underlying factors currently inhibiting performance.

Improved analytics and access to big data

Given the laboratory’s role as a primary source, its impact can be derived from the wealth of real-time patient data collected from numerous tests. In a more value-based setting, the laboratory’s job would be to provide HCPs with data and insight that could be used proactively and predictively for prognosis. Improved analytics and IT infrastructure would also play a pivotal role in delivering a more personalized patient-centric approach.

In the survey, most executives, HCPs, and laboratory directors agreed that the current usage of data is sub-optimal: It is largely retrospective, instead of proactive or predictive. Yet, as Figure 6 (on the next page) demonstrates, the potential of the laboratory to influence and implement analytical tools is undisputed, especially by executives.

“[If we partnered with a medical practice or healthcare center, we would be more privy to diagnostic information and could potentially obtain alignment with other stakeholders to improve patient outcomes at controlled long-term costs.”

Leading Insurer, Brazil
One of the first elements needed to achieve consistent value is a standardized set of measurements linked to larger-scale patient KPIs and overall satisfaction. Following models established by entities, such as the International Consortium for Health Outcomes Measurement (ICHOM), this can be done by collecting evidence-based outcomes data and then interacting with HCPs, insurers, and payers to understand which are important to each group and, ultimately, beneficial for patients.

Though this appears a daunting task, experts offer numerous practical recommendations to follow:

- Outcomes need not represent final “end-goal” outcomes. Paul Epner of the Society to Improve Diagnosis in Medicine suggests measuring a more “intermediate” outcome that focuses on measuring the time from the HCP’s test order to its test retrieval. The timeliness of the full delivery, however, is still dependent on successful multidisciplinary interaction and involvement across the patient-care pathway. In this sense, some key intermediate outcomes could include time to diagnosis, accuracy of diagnosis, and completeness of diagnosis.

- The role of evidence-based KPIs can be enlarged. One expert interviewed from a top provider in the U.S. highlighted the importance of these metrics in facilitating more accurate diagnoses. They also support payer efforts to assess the value of new testing and to adjust the risk adjustment mechanism accordingly.

One example in practice is tracking the percentage of diabetic patients receiving timely HbA1c tests. In Australia, the National Academy of Clinical Biochemistry employs evidence-based practice guidelines, encouraging systematic, appropriate HbA1c testing methods and providing a range of suitable glucose measurement and HbA1c levels for diabetic patients. The resulting evidence of experience—whether a greater likelihood of diagnosis in an emergency care setting (as cited earlier) or a lack of impact in other point-of-care environments—helps drive more effective guidelines.

Companies in the private sector are already collaborating with payers, providers, and laboratories to use analytics to provide better patient prognoses. Start-up Beijing Koboro Health Science and Technology has developed an application, called Daxia Health, that processes large data sets from app users that can be subsequently validated by physicians.

In the United States, there has been marked growth in machine learning and artificial intelligence (AI) to make better prognostic decisions for providers and payers. However, to date, developments in AI are in an incipient stage and require more work, particularly in how output can be effectively tied back to care decision making. As HCPs become more willing to accept AI as relevant to patient treatment decisions, clinical laboratories can serve as bridges for this transition by providing credible and actionable analysis.

This last point is especially true when taking into account the importance of looking holistically at a patient’s health. Unlike many providers and HCPs, which tend to specialize in specific therapeutic areas, laboratories for decades have taken a disease-agnostic view and, thus, have the potential to collect, analyze, and provide insight across the spectrum of interrelated health factors. In addition, with the rise of multiple chronic conditions, where clusters of diseases have common risk factors and synergistic relationships, being able to diagnose early is critical, given the proven exponential growth in the cost of treatment.
Finally, as with many elements of the healthcare ecosystem, a key step for the laboratory in enhancing its ability to use analytics involves education, incorporating tools for data assimilation and aggregation at the undergraduate level. Mike Hallworth, International Federation of Clinical Chemistry and Laboratory Medicine, asserted: “We need to make sure that trainees in laboratory medicine understand the principles of testing and the techniques for analyzing and synthesizing data.”

**Integrating stakeholders as equal partners in delivery**

While involvement in KPI setting and capabilities concerning data analytics is a key building block in preparing laboratories for a future impactful role (as shown in Figure 7), the research indicates a broader level of integration is required to achieve any substantial change in the status quo. Grounded in a common purpose of delivering better outcomes, this entails two critical steps:

- Transparent communication and consistent flow of information among stakeholders
- Cultural change in how the lab is viewed as an entity that can positively influence decisions

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**GEOGRAPHIC INSIGHTS**

**EXAMPLES OF DATA ANALYTICS:**

**U.K.** The Atlas of Variation is a tool assessing unwanted outcome variation, identifying how disease patterns vary across demographics.

**BRAZIL** Labs like DASA have made efforts to identify KPIs and to analyze which tests yield clinical and financial effectiveness.*

**VIETNAM** The Oxford University Clinical Research Unit aggregates data on infectious diseases to frame future risk trends by patient type.

At the most basic level, clinical laboratories must take the lead in developing a continual process of disseminating knowledge across the care pathway. This involves providing HCPs with a better understanding of diagnostic standards (including new technologies), a need illustrated in Figures 8 and 9. To ensure sufficient buy-in, labs and executives need to develop and share evidence about the impact of tests and interpretations, not just with HCPs but also with payers, which will help enable better decision making across the continuum of care.

In addition, labs can and should act as conduits for physician and patient interaction. Given the clear and growing trend of patients seeking blood tests without a doctor’s recommendation (i.e., 49 percent of patients surveyed reported doing so for general wellness issues, and 29 percent reported doing so for tests related to cancer markers), the lab can play a central role in integrating patient (perceived) needs with guidance from HCPs. This also will generate a greater level of satisfaction among stakeholders, especially as patients increasingly tend toward more actively managing their own health.

At the same time, shifting away from past interactions toward an integrated approach requires leadership and the establishment of shared accountabilities. While a majority of executives believe the lab performs one of the most important functions in delivering improved KPIs, this must be reinforced through action. A clear and positive signal would simply be addressing the investment gap in clinical laboratories in capabilities, new technologies, and the use of data to enhance the value proposition of laboratories. This should be complemented by a well-defined directive for the future involvement of labs in achieving VBHC goals and expected behaviors from stakeholders, as well as through implemented processes, to ensure a smooth path to a new norm.

One stakeholder likely to play a role in this transition is an unlikely source. As shown in Figures 8 and 9, there is a clear trend of greater education by patients regarding their own health; availability of care options will lead to multiple points of connection with health delivery. With nearly two-thirds of patients reporting value in self-directed testing and almost three-fifths willing to pay more for a more detailed lab report, the positioning of labs as equal partners may be facilitated by new models of healthcare interaction.

**Addressing likely sources of resistance to change**

The actions listed (concerning KPI standards, data analytics, and shared accountabilities) will go a long way toward facilitating a better environment for labs to play an elevated role in ensuring the success of the value-based healthcare movement. Nevertheless, numerous points in the current ecosystem could act as significant barriers to implementing this proposed approach.

**Laboratory behavioral readiness in evolution toward value is still a work in progress**

The integration, empowerment, and accountability of important outcome metrics are major gaps in the laboratory’s transition to value-based healthcare. Expanding capabilities is another critical building block that requires investment and effort. From a current service offering perspective, labs only consistently report readiness for basic areas: speed, accuracy,
“We need to spend more time understanding the link between testing and outcomes. This requires evidence-based studies in which a particular test is applied in a specified clinical context and the effect of testing on defined outcome parameters is measured. That’s the key to demonstrating the value of laboratory medicine.”

Mike Hallworth, International Federation of Clinical Chemistry and Laboratory Medicine

“The current system is one where labs are simply tasked to execute tests. They do not know much about the patient’s medical history .... Physicians are the main conduits of decision making. The result is labs often have little accountability in the patient’s overall health.”

quality, and safety of test results. Only a small percentage of those surveyed believe that clinical decision support tools are currently offered by the lab.

A primary driver of limited capabilities is antiquated pricing models. Though some progressive labs have adopted new funding mechanisms to reflect the true value they bring to the care continuum, the majority are constricted by existing reimbursement systems. In Brazil, services offered by laboratories are constrained by what insurance companies are willing to cover (i.e., those preapproved for reimbursement by the Brazilian Medical Association). This indicates challenging financial conditions for supporting investments in capabilities required to reach the next stage of clinical laboratory evolution.

While there is some alignment on the opportunity for labs to provide value-added services, such as appropriate test utilization management, research suggests questions concerning existing lab capacity. Most lab directors believe they do not have the current capabilities to deliver value-added services or to critically impact anything beyond safe and timely testing. Though data skills in the lab are naturally more advanced than those of other stakeholders (given the typical background of lab personnel), only 18 percent feel labs are capable of delivering high-quality solutions for such categories as precision medicine.

The skills gap is not just restricted to the laboratory environment; as shown in Figure 2 (found on page 13), there is a sizeable divide between the desire of HCPs to receive training and lab directors actually providing it. The importance of this divergence is reflected in lab directors’ level of certainty (54 percent of those surveyed) that HCPs are adhering to the correct diagnostic standards. While no single stakeholder group is responsible for this lack of education, it can and will serve as a barrier to the most accurate diagnosis. This ultimately will have repercussions for the most commonly shared KPI, patient satisfaction, especially in markets where the fragmentation of care regularly forces frustrated patients to act as their own repositories of medical knowledge.

Underlying weaknesses in health systems and delivery further hinder the lab’s elevation

Still, many potential obstacles to progress remain:

• Imperfections of IT systems (including legacy electronic health records or failed implementation of new platforms) in facilitating real-time data sharing across established silos and necessary stakeholders
• Insufficient educational backgrounds and preparedness (particularly for soft skills) of key lab personnel to assess and effectively communicate key insights
• Persistence in the fragmented delivery and management of care, achieving integration for specific disease conditions rather than centering on patients
• Inability of all stakeholders to have a consistent and holistic view of longitudinal patient journeys (and related data)

• Continued use of incentive schemes that reward behavior not focused on a shared set of outcomes but rather on historical volume-based objectives

A core concern is laboratories’ future financial dynamics and the shift away from a singular focus on cost efficiencies. The increased pressure of health budgets around the world will likely limit whatever additional investments can be made in laboratories. This implies that the only successful business model will be based on performance (and even risk sharing), further emphasizing the importance of linking laboratory activities with key health system metrics.

Related to this, the point of greatest resistance to the proposed shift will be the lack of definitive evidence demonstrating the true impact labs offer to the value equation. In his paper, Paul Epner noted that one of the challenges with the current model is that laboratory clinicians have not sufficiently articulated the negative consequences and unsustainability of the model to physicians and the health system. Reverting this understanding requires not just educating stakeholders but also fostering greater awareness of the implications of both action (how labs can positively influence outcomes) and inaction (how status quo decision making contributes to value leakages).

However, the chance to present this evidence and integrate real-time data insights into clinical decision making will be restricted if the predominant model of the laboratory is outsourcing. While this approach can present immediate advantages (and instill stronger competitive
forces into the marketplace), it can hold back the necessary integration of insights into the care continuum. This not only further silos valuable data and knowledge from those who need it most, but it also risks losing that knowledge altogether.

Policy can facilitate the proper environment for laboratories to thrive

By design, public sector actors are not a focus of this research, given the challenging policy environment surrounding healthcare, difficult short-term budget decisions, and sometimes polarizing viewpoints. Nevertheless, policymakers can and should play a significant role in this process, creating standards for data, facilitating information sharing, ensuring a more prominent role for laboratories in clinical and patient decision making, and enabling fair value-based models. The countries in which governments dominate health systems are poised to be leaders in this space; however, the push for action is more likely to occur by engaging all other stakeholders to achieve a shared consensus view and then engaging policymakers.

A review of existing health policies and initiatives demonstrates that few countries have established the necessary building blocks to support wide adoption of value principles. Figure 10 highlights this lack of progress, as the EIU found that only two countries (South Korea and Sweden) have systems for care guidelines that both grade evidence and move toward outcome-based healthcare. This indicates a variety of existing gaps (high-level VBHC policies, outcome data collection, coordinated care, and payment schemes) that need to be addressed in conjunction to create an environment conducive to VBHC having a major impact.

While the use of data has become a primary focus for health policy, very few countries have been able to tackle the barriers identified in Chapter 1 of this study. In the United States, one

Figure 10: Global developments in VBHC evidence guidelines

Source: Economist Intelligence Unit.
interviewed healthcare professional called for the introduction of new policies to alter the current risk adjustment mechanism through the capture and use of patient-specific data. “What would be more ideal is if there were policies that could advocate for the introduction of patient identifiers, which would channel all patient-specific health records to one unique number/identifier to make it easier for any lab to better diagnose patient conditions,” he said. This would enable stakeholders to make more informed judgments about the overall health of their populations and offer patients more control over their data and related diagnostic/treatment processes by determining who could access their records.

Other geographies, such as Western Europe, are in a better position to harmonize this collection of patient information, given the greater centralization of local health systems. Nevertheless, with the rise of cyberattacks and greater dependence on cloud-based data systems, all countries need to find a balance between maintaining a common level of privacy and leveraging the power of real-world patient population data. For labs striving to be conduits for valuable clinical data points, taking a perspective on how to resolve this important challenge appears critical.

Lastly, all stakeholders—labs included—need to continue to advance the dialogue with policymakers on the true value of optimal healthcare. Literature has demonstrated a clear linkage between healthy populations and upstream factors, such as productivity and educational attainment, suggesting the value of specific interventions is not limited to health benefits. One EIU study showed the introduction of the HbA1c blood test for diabetes in Japan led to reduced worker absenteeism and, thus, an economic gain of nearly $2,400 per patient per year. As non-health policymakers increasingly wield influence over healthcare budget decisions, reframing the perception of value appears critical.
Path for success exists for the lab in VBHC, but it requires change now

This study highlights the importance of incorporating the clinical laboratory into the VBHC movement. Although efforts to eliminate waste and improve patient outcomes have positively contributed to this, labs remain behind the scenes, tasked only with processing larger test volumes at greater efficiencies.

The way forward, as outlined in Table 1, should seek to revert this commoditized positioning and enable the multiple benefits the laboratory can offer for enhanced patient and clinical decision making:

- Access to a wealth of diagnostic data and knowledge
- Ability to define, interpret, and drive proper testing
- Consistent education on the latest diagnostic techniques and learnings

This requires a substantive behavioral change in today’s health value chain. Actions required include incorporating laboratories into the health system KPI process, a greater capacity for data and analytics, the seamless flow of knowledge dissemination, and a clear sense of shared accountability. Special focus should remain on developing a stronger level of trust between clinical laboratories and HCPs, as historically these groups have experienced a rather siloed relationship.

While these goals have significant hurdles, the research demonstrates that stakeholders are ready and willing to integrate labs in this much-needed shift toward VBHC. HCPs and executives believe the lab’s future role in better healthcare decision making is not only necessary but, rather, imminent. While continuing to deliver operational excellence remains a fundamental goal, labs must also be enabled as integral partners in facilitating and achieving dynamic, evidence-driven patient-centric care.

According to WHO, 31 million cases of sepsis occur every year, resulting in 6 million deaths. With the right diagnosis and treatment, many of those could be prevented.

“Good quality is less costly because of more accurate diagnoses, fewer treatment errors, lower complication rates, faster recovery, less invasive treatment, and the minimization of the need for treatment. More broadly, better health is less expensive than illness.”

*Michael Porter, “Redefining Health Care: Creating Value-Based Competition on Results*
The underlying forces at play within healthcare and society will undoubtedly generate change; this can be managed proactively by laboratories or eventually be imposed on them. In an environment with persistent chronic conditions and subsequently rising healthcare costs, the path toward sustainability will occur one way or another. In this sense, maintaining the status quo risks further commoditization of lab services.

<table>
<thead>
<tr>
<th>CALL TO ACTION</th>
<th>KEY PRINCIPLES AND PREMISES</th>
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<tr>
<td>Develop a clear link between laboratories and outcomes by standardizing and measuring laboratory-influenced intermediate KPIs.</td>
<td>Premise: The move from volume to value is inevitable.</td>
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<td>Key principle: All relevant stakeholders (payers, providers, HCPs, external institutions) must agree on the intermediate KPIs that are aligned with overall hospital KPIs.</td>
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<td>Create and effectively share:</td>
<td>Premise: Laboratories are replete with patient and population data. This data is ripe with potential for determining disease susceptibilities, incidence, and prevalence patterns, as well as growth trends. Additionally, creating innovative algorithms can help labs effectively mine and use relevant diagnostic data.</td>
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<tr>
<td>• Real-time data analytics (proactive and predictive).</td>
<td>Key principle: All relevant stakeholders (HCPs, physicians, payers, executives, patients) must use data analytics and information to provide more targeted, informed prognoses to patients.</td>
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<tr>
<td>• Patient and population-specific information.</td>
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<tr>
<td>• New data-mining algorithms.</td>
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<tr>
<td>Encourage laboratory standards and education.</td>
<td>Premise: Improved patient outcomes are a function of greater and more timely diagnostic accuracy, which can be achieved by developing clinician competencies in extracting and interpreting test data.</td>
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<td></td>
<td>Key principle: Placing emphasis on lab standards and education would develop competencies to better analyze data, improve diagnoses, increase lab accountability in the overall patient-care pathway, and ultimately benefit outcomes.</td>
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<td>Integrate all stakeholders along the patient-care pathway through transparent communication.</td>
<td>Premise: Providing sustained patient value depends on regular communication and integration across the patient-care pathway.</td>
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<td>Key principle: For laboratories to effectively communicate their value proposition to other stakeholders in the clinical pathway, they must better coordinate with the overall healthcare system.</td>
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<td>Position stakeholders as equal partners in delivery.</td>
<td>Premise: A transition from volume to value can only be sustained if all stakeholders are equally accountable in healthcare delivery.</td>
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<td>Key principle: There is a shared responsibility across the patient-care pathway to provide laboratories with opportunities to contribute to overall patient outcomes.</td>
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In the end, one takeaway from this study centers simply on the need for dialogue. This entails labs being at the center of conversations on future value agendas to present the case for the importance of proper diagnostic decisions for overall outcomes. It also includes others seeking to learn from the valuable knowledge labs retain. “Going it alone” in a world where care becomes more complex every day is just not feasible. Thus, as a starting point, aligning perceptions, needs, and reality is the best first step toward a better path for proper decision making.

Maintaining the status quo risks further commoditization of lab services.

### EXAMPLES OF POSSIBLE ACTIONS AND CORRESPONDING ACTORS

**Executives:** Execute a mandate to integrate labs into the KPI-setting process. This entails establishing an environment to regularly check KPI performance.

**HCPs and labs:** Start measuring a standardized set of intermediate KPIs. These may include clinical lab KPIs, like test appropriateness, communication of results across the diagnostic pathway, and test turnaround time, as well as wider scope patient KPIs that measure progress across the entire end-to-end patient-care pathway.

**Executives:** Invest time and resources to centralize data analytics systems and capacity in the lab, ensuring this function is set up for success in achieving the vision of its role in data analytics.

**Labs:** Use analytic tools proactively and predictively to more precisely assess future outcomes (specific to each patient) and anticipate trends in disease coverage, sharing both retrospective and predictive data along the patient-care pathway.

**HCPs:** Use lab-provided data to more accurately diagnose and prescribe treatment.

**Payers:** Use clinician-provided data to more accurately determine how to link reimbursement coverage to actual and expected patient outcomes.

**Executives:** Provide structure and forums to foster standards development.

**Labs:** Collaborate with data scientists to enhance current competencies, extract and interpret relevant clinical data for improved decision making, and expand outreach role for labs.

**Executives:** Provide leadership to ensure proper integration, establishing new protocols to guide healthier interaction and break down existing silos.

**Payers, HCPs, labs:** Foster multidisciplinary interaction and involvement across the patient-care pathway to ensure timely healthcare delivery, from diagnosis to treatment and, eventually, patient monitoring. This should include sharing new diagnostic standards, testing technologies, and patient disease incidence records among payers, physicians, and laboratory clinicians.

**Labs, HCPs:** Continue to enhance, emphasize, and communicate labs’ value proposition to other stakeholders by providing guidance on test interpretation, actively integrating and communicating across stakeholder groups, sharing information through data analytics, and achieving clinical lab KPIs in a timely manner.

**Executives, payers:** Shift perspective from labs’ role as a back-end function to a more value-added service by fostering new models (operational and financial) that support the development and utilization of evidence related to labs’ impact on KPIs.
“Breaking Down Barriers in Healthcare” is a report by Abbott, written by the Economist Intelligence Unit. It assesses the state of clinical laboratories today in the healthcare ecosystem, the perceptions and actions that drive behavior across different stakeholders, and the future role labs can play in delivering improved value.

The report draws upon secondary research, quantitative surveys across key stakeholders, and in-depth interviews with payers, academia, government entities, and thought leaders. We would like to thank the following experts for their time (listed alphabetically):

a. Paul Epner, Co-Founder, Society to Improve Diagnosis in Medicine

b. Mike Hallworth, Chair, Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes, International Federation of Clinical Chemistry and Laboratory Medicine

c. Daniel Leveson, Deputy Director of Strategy and Business Development, Buckinghamshire NHS Trust, National Health Service

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